



**EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to *Lactobacillus johnsonii* NCC 533 (La1) (CNCM I-1225) and improving immune defence against pathogenic gastro-intestinal microorganisms (ID 896), and protection of the skin from UV-induced damage (ID 900) pursuant to Article 13(1) of Regulation (EC) No 1924/2006**

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## SCIENTIFIC OPINION

### **Scientific Opinion on the substantiation of health claims related to *Lactobacillus johnsonii* NCC 533 (La1) (CNCM I-1225) and improving immune defence against pathogenic gastro-intestinal microorganisms (ID 896), and protection of the skin from UV-induced damage (ID 900) pursuant to Article 13(1) of Regulation (EC) No 1924/2006<sup>1</sup>**

**EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)<sup>2,3</sup>**

European Food Safety Authority (EFSA), Parma, Italy

#### SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies was asked to provide a scientific opinion on a list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006. This opinion addresses the scientific substantiation of health claims in relation to *Lactobacillus johnsonii* NCC 533 (La1) (CNCM I-1225) and improving immune defence against pathogenic gastro-intestinal microorganisms, and protection of the skin from UV-induced damage. The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The food constituent that is the subject of the health claim is *Lactobacillus johnsonii* NCC 533 (La1) (CNCM I-1225). The Panel considers that *Lactobacillus johnsonii* NCC 533 (La1) (CNCM I-1225) is sufficiently characterised.

#### **Improving immune defence against pathogenic gastro-intestinal microorganisms**

The claimed effect is “natural defence/immune system”. The target population is assumed to be the general population. In the context of the clarifications from Member States and the references provided, the Panel assumes that the claimed effect refers to improving immune defence against

<sup>1</sup> On request from the European Commission, Question No EFSA-Q-2008-1683, EFSA-Q-2008-1687, adopted on 25 March 2011.

<sup>2</sup> Panel members: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Hannu Korhonen, Pagona Lagiou, Martinus Løvik, Rosangela Marchelli, Ambroise Martin, Bevan Moseley, Monika Neuhäuser-Berthold, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Stephan Strobel, Inge Tetens, Daniel Tomé, Hendrik van Loveren and Hans Verhagen. Correspondence: [nda@efsa.europa.eu](mailto:nda@efsa.europa.eu)

<sup>3</sup> Acknowledgement: The Panel wishes to thank for the preparatory work on this scientific opinion: The members of the Working Group on Claims: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Marina Heinonen, Hannu Korhonen, Martinus Løvik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Inge Tetens, Hendrik van Loveren and Hans Verhagen. The members of the Claims Sub-Working Group on Gut/Immune: Jean-Louis Bresson, Maria Carmen Collado, Miguel Gueimonde, Daisy Jonkers, Martinus Løvik, Bevan Moseley, Maria Saarela, Seppo Salminen, Yolanda Sanz, Stephan Strobel, Daniel Tomé and Hendrik van Loveren.

pathogenic gastro-intestinal microorganisms. The Panel considers that improving immune defence against pathogenic gastro-intestinal microorganisms is a beneficial physiological effect.

No human studies from which conclusions could be drawn for the scientific substantiation of the claim were provided.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of *Lactobacillus johnsonii* NCC 533 (La1) (CNCM I-1225) and improving immune defence against pathogenic gastro-intestinal pathogens.

### **Protection of the skin from UV-induced damage (ID 900)**

The claimed effect is “skin health”. The target population is assumed to be the general population. In the context of the clarifications provided by Member States, the Panel assumes that the claimed effect refers to protection of the skin from UV-induced damage. The Panel considers that protection of the skin from UV-induced damage is a beneficial physiological effect.

No human studies from which conclusions could be drawn for the scientific substantiation of the claim were provided.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of *Lactobacillus johnsonii* NCC 533 (La1) (CNCM I-1225) and protection of the skin from UV-induced damage.

### **KEY WORDS**

*Lactobacillus johnsonii* NCC 533 (La1) (CNCM I-1225), immune, gastro-intestinal pathogens, skin, UV exposure, health claims.

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## **BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION**

See Appendix A

## **TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION**

See Appendix A

## **EFSA DISCLAIMER**

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## INFORMATION AS PROVIDED IN THE CONSOLIDATED LIST

The consolidated list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006<sup>4</sup> submitted by Member States contains main entry claims with corresponding conditions of use and literature for similar health claims. EFSA has screened all health claims contained in the original consolidated list of Article 13 health claims which was received by EFSA in 2008 using six criteria established by the NDA Panel to identify claims for which EFSA considered sufficient information had been provided for evaluation and those for which more information or clarification was needed before evaluation could be carried out<sup>5</sup>. The clarifications which were received by EFSA through the screening process have been included in the consolidated list. This additional information will serve as clarification to the information originally provided. The information provided in the consolidated list for the health claims which are the subject of this opinion is tabulated in Appendix C.

## ASSESSMENT

### 1. Characterisation of the food/constituent

The food constituent that is the subject of the health claims is “*Lactobacillus johnsonii* NCC 533 (La1) (CNCM I-1225)”, (hereafter *L. johnsonii* NCC 533 or *L. johnsonii* La1).

The identification/characterisation of the strain *L. johnsonii* NCC 533 has not been included in the studies provided but different studies on phenotypic and genotypic identification/characterisation can be found in the literature (Berger et al., 2007; Ventura et al., 2004). In addition, the genome sequence of *L. johnsonii* NCC 533 is publicly available at the NCBI database (accession NC\_005362) (Pridmore et al., 2004). A culture collection number from the Collection Nationale de Cultures de Microorganismes (CNCM) was also provided. The strain *Lactobacillus acidophilus* La1 has been re-classified as *L. johnsonii* La1.

The Panel considers that the food constituent, *Lactobacillus johnsonii* NCC 533 (La1) (CNCM I-1225), which is the subject of the health claims, is sufficiently characterised.

### 2. Relevance of the claimed effect to human health

#### 2.1. Improving immune defence against pathogenic gastro-intestinal microorganisms (ID 896)

The claimed effect is “natural defence/immune system”. The Panel assumes that the target population is the general population.

In the context of the clarifications from Member States and the references provided, the Panel assumes that the claimed effect refers to improving immune defence against pathogenic gastro-intestinal microorganisms.

The Panel considers that improving immune defence against pathogenic gastro-intestinal microorganisms is a beneficial physiological effect.

<sup>4</sup> Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. OJ L 404, 30.12.2006, p. 9–25.

<sup>5</sup> EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2011. General guidance for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims. EFSA Journal, 9(4):2135, 24 pp.

## **2.2. Protection of the skin from UV-induced damage (ID 900)**

The claimed effect is “skin health”. The Panel assumes that the target population is the general population.

In the context of the clarifications provided by Member States, the Panel assumes that the claimed effect refers to protection of the skin from UV-induced damage.

The Panel considers that protection of the skin from UV-induced damage is a beneficial physiological effect.

## **3. Scientific substantiation of the claimed effect**

### **3.1. Improving immune defence against pathogenic gastro-intestinal microorganisms (ID 896)**

Among the references provided in relation to the claim, six citations were incomplete and the corresponding references could not be retrieved, the full texts of four references were not accessible to the Panel after every reasonable effort was made to retrieve them, three review papers did not provide original data, one reference was in Japanese and no translation into an EU language was available to the Panel, one human study did not address outcomes related to the claimed effect, three human studies addressed the effects of different combinations of food constituents and did not allow conclusions to be drawn on the effects of *L. johnsonii* La1 alone (e.g. *L. johnsonii* La1 plus *S. thermophilus* without controlling for the effect of *S. thermophilus* alone), and one human study used an administration route (i.e. via naso-gastric tube) which is not relevant for the substantiation of a claim on a food for oral consumption. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

The remaining references included six human studies, 11 animal studies and 26 *in vitro* studies.

In a randomised, double-blind, placebo-controlled cross-over study (Yamano et al., 2006), 22 young healthy Japanese women (aged 20-22 years) received either 120 mL of fermented milk with *L. johnsonii* La1 (NCC 533) ( $1 \times 10^9$  CFU/day) and *Streptococcus thermophilus* ( $1 \times 10^8$  CFU/day) or the same amount of fermented (placebo) milk with *S. thermophilus* ( $1 \times 10^8$  CFU/day) only, for 21 days each with a wash-out period of 29 days in between. The effect of *L. johnsonii* La1 (NCC 533) on the intestinal microbiota (15 microorganisms or groups thereof) was investigated, including the appearance rate and numbers of lecithinase-positive *Clostridium* in the faeces. The Panel notes that the high number of primary outcomes tested was not taken into account in the statistical analysis, and that the number of lecithinase-positive *Clostridium* carriers was low. Therefore, it cannot be excluded that the borderline statistical significance of the difference in the number of lecithinase-positive *Clostridium* reported between the intervention and placebo groups is a chance finding. The Panel considers that no conclusions can be drawn from this study for the scientific substantiation of the claim.

Brunser (2000) reported on a partially randomised and blinded study on anti-polio secretory IgA in saliva after oral polio vaccination in groups of infants (116 were enrolled) between four and six months old, in which the primary outcome was the safety of the formula and the secondary outcomes included the immune response to oral polio vaccination (IgA in saliva) and faecal bacterial composition. In another study, Brunser et al. (2006) evaluated the effect of *L. johnsonii* La1 on faecal bacterial counts in 90 infants (around 3.5 months of age). The Panel notes that the immune system in early childhood is still developing, and that the microbiota is different in composition, diversity, stability and evolution from that of adults. The Panel considers that the evidence provided does not establish that data from these study populations can be extrapolated to the general population.

In a double-blind, placebo-controlled study by Donnet-Hughes et al. (1999), a total of 42 volunteers were randomised to receive *S. thermophilus* only, *S. thermophilus* with  $10^9$  CFU *L. johnsonii* La1, or *S. thermophilus* with  $10^8$  CFU *L. johnsonii* La1 daily for three weeks after a 3-week run-in phase in which all volunteers received milk. Outcome measures included phagocytic activity and leukocyte oxidative burst. Two other human intervention studies with a parallel-group design (Schiffrin et al., 1995; 1997) in which individuals were given fermented milk with *L. acidophilus* La1 (re-classified as *L. johnsonii* La1) ( $7 \times 10^{10}$  CFU/day) or *Bifidobacterium bifidum* strain Bb-12 (currently *B. animalis*,  $1 \times 10^{10}$  CFU/day) for three weeks were provided. Outcome measures were lymphocyte subsets and leukocyte phagocytic activity. In these studies, only within-group (and not between-group) comparisons were reported for the outcome measures. The Panel considers that no conclusions can be drawn from these studies for the scientific substantiation of the claim.

Eleven animal studies on the effects of *L. johnsonii* La1 on the development and function of the immune system in gnotobiotic mice, as well as on oral tolerance, antibody production, and other parameters of immune function in mice were cited. None of the studies addressed outcomes directly related to pathogens. The *in vitro* studies dealt with the proliferative and cytokine responses of various immune and epithelial cell types, cellular interactions, bacterial adhesion to epithelial cells and production of bacteriocins. The Panel considers that evidence provided in animal and *in vitro* studies is not sufficient to predict the occurrence of an effect of *L. johnsonii* La1 consumption on improving immune defence against pathogens in humans.

The Panel notes that no human studies from which conclusions could be drawn for the scientific substantiation of the claim were provided.

The Panel concludes that a cause and effect relationship has not been established between the consumption of *Lactobacillus johnsonii* NCC 533 (La1) (CNCM I-1225) and improving immune defence against pathogenic gastro-intestinal microorganisms.

### **3.2. Protection of the skin from UV-induced damage (ID 900)**

Among the references provided in relation to the claim were unpublished reports, meeting abstracts or posters, which were either not accessible to the Panel or did not contain sufficient information for a full scientific evaluation. One animal study on the development of atopic dermatitis did not address outcomes related to the claimed effect. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

In a double-blind, randomised, placebo-controlled human intervention study (Peguet-Navarro et al., 2008), 54 healthy male volunteers (aged 20 to 40 years) received daily oral supplementation with either *L. johnsonii* La1 ( $1 \times 10^{10}$  CFU, n=27) or placebo (maltodextrin, n=27) for 66 days. Suction blister roofs and skin biopsies were taken from the right and left buttocks of each volunteer at baseline, and the UV minimal erythral dose (MED) was determined. On day 56, the volunteers were exposed to 1.5 MED twice within 10 hrs on a 10x10 cm area on the right buttock from a 1,000 W xenon solar simulator, with an exposure spectrum according to the standards for determining sun protection factors. On days 1, 4 and 10 post-irradiation, suction blister roofs and biopsies were again collected from the right and left buttocks. Results were based on comparisons between exposed and un-exposed areas for each subject, and included immuno-histochemical analysis (scoring) of a number of cellular markers performed double-blind by a single examiner. In addition, epidermal cells (not further characterised) were isolated, and mixed epidermal cell-(allogenic) lymphocyte reactions were performed with lymphocytes from three unrelated allogeneic donors. The Panel notes that no functional studies on the immune response against foreign antigens were provided. The Panel further notes that in the statistical analysis only within-group comparisons were reported, with no statistical comparison between the two groups. The Panel considers that no conclusions can be drawn from this study for the scientific substantiation of the claim.



One animal study on the effect of *L. johnsonii* on UV-induced immunosuppression was provided. The Panel considers that evidence provided in animal studies is not sufficient to predict the occurrence of an effect of *Lactobacillus johnsonii* La1 consumption on protection of the skin from UV-induced damage in humans.

The Panel concludes that a cause and effect relationship has not been established between the consumption of *Lactobacillus johnsonii* NCC 533 (La1) (CNCM I-1225) and protection of the skin from UV-induced damage.

## CONCLUSIONS

On the basis of the data presented, the Panel concludes that:

- The food constituent, *Lactobacillus johnsonii* NCC 533 (La1) (CNCM I-1225), which is the subject of the health claims, is sufficiently characterised.

### Improving immune defence against pathogenic gastro-intestinal microorganisms (ID 896)

- The claimed effect is “natural defence/immune system”. The target population is assumed to be the general population. Improving immune defence against pathogenic gastro-intestinal microorganisms is a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of *Lactobacillus johnsonii* NCC 533 (La1) (CNCM I-1225) and improving immune defence against pathogenic gastro-intestinal microorganisms.

### Protection of the skin from UV-induced damage (ID 900)

- The claimed effect is “skin health”. The target population is assumed to be the general population. In the context of the clarifications provided by Member States, it is assumed that the claimed effect refers to protection of the skin from UV-induced damage. Protection of the skin from UV-induced damage is a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of *Lactobacillus johnsonii* NCC 533 (La1) (CNCM I-1225) and protection of the skin from UV-induced damage.

## DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-1683, EFSA-Q-2008-1687). The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The full list of supporting references as provided to EFSA is available on: <http://www.efsa.europa.eu/panels/nda/claims/article13.htm>.

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## APPENDICES

### APPENDIX A

#### BACKGROUND AND TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

The Regulation 1924/2006 on nutrition and health claims made on foods<sup>6</sup> (hereinafter "the Regulation") entered into force on 19<sup>th</sup> January 2007.

Article 13 of the Regulation foresees that the Commission shall adopt a Community list of permitted health claims other than those referring to the reduction of disease risk and to children's development and health. This Community list shall be adopted through the Regulatory Committee procedure and following consultation of the European Food Safety Authority (EFSA).

Health claims are defined as "any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health".

In accordance with Article 13 (1) health claims other than those referring to the reduction of disease risk and to children's development and health are health claims describing or referring to:

- a) the role of a nutrient or other substance in growth, development and the functions of the body; or
- b) psychological and behavioural functions; or
- c) without prejudice to Directive 96/8/EC, slimming or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet.

To be included in the Community list of permitted health claims, the claims shall be:

- (i) based on generally accepted scientific evidence; and
- (ii) well understood by the average consumer.

Member States provided the Commission with lists of claims as referred to in Article 13 (1) by 31 January 2008 accompanied by the conditions applying to them and by references to the relevant scientific justification. These lists have been consolidated into the list which forms the basis for the EFSA consultation in accordance with Article 13 (3).

#### ISSUES THAT NEED TO BE CONSIDERED

##### IMPORTANCE AND PERTINENCE OF THE FOOD<sup>7</sup>

Foods are commonly involved in many different functions<sup>8</sup> of the body, and for one single food many health claims may therefore be scientifically true. Therefore, the relative importance of food e.g. nutrients in relation to other nutrients for the expressed beneficial effect should be considered: for functions affected by a large number of dietary factors it should be considered whether a reference to a single food is scientifically pertinent.

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<sup>6</sup> OJ L12, 18/01/2007

<sup>7</sup> The term 'food' when used in this Terms of Reference refers to a food constituent, the food or the food category.

<sup>8</sup> The term 'function' when used in this Terms of Reference refers to health claims in Article 13(1)(a), (b) and (c).

It should also be considered if the information on the characteristics of the food contains aspects pertinent to the beneficial effect.

#### **SUBSTANTIATION OF CLAIMS BY GENERALLY ACCEPTABLE SCIENTIFIC EVIDENCE**

Scientific substantiation is the main aspect to be taken into account to authorise health claims. Claims should be scientifically substantiated by taking into account the totality of the available scientific data, and by weighing the evidence, and shall demonstrate the extent to which:

- (a) the claimed effect of the food is beneficial for human health,
- (b) a cause and effect relationship is established between consumption of the food and the claimed effect in humans (such as: the strength, consistency, specificity, dose-response, and biological plausibility of the relationship),
- (c) the quantity of the food and pattern of consumption required to obtain the claimed effect could reasonably be achieved as part of a balanced diet,
- (d) the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.

EFSA has mentioned in its scientific and technical guidance for the preparation and presentation of the application for authorisation of health claims consistent criteria for the potential sources of scientific data. Such sources may not be available for all health claims. Nevertheless it will be relevant and important that EFSA comments on the availability and quality of such data in order to allow the regulator to judge and make a risk management decision about the acceptability of health claims included in the submitted list.

The scientific evidence about the role of a food on a nutritional or physiological function is not enough to justify the claim. The beneficial effect of the dietary intake has also to be demonstrated. Moreover, the beneficial effect should be significant i.e. satisfactorily demonstrate to beneficially affect identified functions in the body in a way which is relevant to health. Although an appreciation of the beneficial effect in relation to the nutritional status of the European population may be of interest, the presence or absence of the actual need for a nutrient or other substance with nutritional or physiological effect for that population should not, however, condition such considerations.

Different types of effects can be claimed. Claims referring to the maintenance of a function may be distinct from claims referring to the improvement of a function. EFSA may wish to comment whether such different claims comply with the criteria laid down in the Regulation.

#### **WORDING OF HEALTH CLAIMS**

Scientific substantiation of health claims is the main aspect on which EFSA's opinion is requested. However, the wording of health claims should also be commented by EFSA in its opinion.

There is potentially a plethora of expressions that may be used to convey the relationship between the food and the function. This may be due to commercial practices, consumer perception and linguistic or cultural differences across the EU. Nevertheless, the wording used to make health claims should be truthful, clear, reliable and useful to the consumer in choosing a healthy diet.

In addition to fulfilling the general principles and conditions of the Regulation laid down in Article 3 and 5, Article 13(1)(a) stipulates that health claims shall describe or refer to "the role of a nutrient or other substance in growth, development and the functions of the body". Therefore, the requirement to

describe or refer to the 'role' of a nutrient or substance in growth, development and the functions of the body should be carefully considered.

The specificity of the wording is very important. Health claims such as "Substance X supports the function of the joints" may not sufficiently do so, whereas a claim such as "Substance X helps maintain the flexibility of the joints" would. In the first example of a claim it is unclear which of the various functions of the joints is described or referred to contrary to the latter example which specifies this by using the word "flexibility".

The clarity of the wording is very important. The guiding principle should be that the description or reference to the role of the nutrient or other substance shall be clear and unambiguous and therefore be specified to the extent possible i.e. descriptive words/ terms which can have multiple meanings should be avoided. To this end, wordings like "strengthens your natural defences" or "contain antioxidants" should be considered as well as "may" or "might" as opposed to words like "contributes", "aids" or "helps".

In addition, for functions affected by a large number of dietary factors it should be considered whether wordings such as "indispensable", "necessary", "essential" and "important" reflects the strength of the scientific evidence.

Similar alternative wordings as mentioned above are used for claims relating to different relationships between the various foods and health. It is not the intention of the regulator to adopt a detailed and rigid list of claims where all possible wordings for the different claims are approved. Therefore, it is not required that EFSA comments on each individual wording for each claim unless the wording is strictly pertinent to a specific claim. It would be appreciated though that EFSA may consider and comment generally on such elements relating to wording to ensure the compliance with the criteria laid down in the Regulation.

In doing so the explanation provided for in recital 16 of the Regulation on the notion of the average consumer should be recalled. In addition, such assessment should take into account the particular perspective and/or knowledge in the target group of the claim, if such is indicated or implied.

## **TERMS OF REFERENCE**

### **HEALTH CLAIMS OTHER THAN THOSE REFERRING TO THE REDUCTION OF DISEASE RISK AND TO CHILDREN'S DEVELOPMENT AND HEALTH**

EFSA should in particular consider, and provide advice on the following aspects:

- Whether adequate information is provided on the characteristics of the food pertinent to the beneficial effect.
- Whether the beneficial effect of the food on the function is substantiated by generally accepted scientific evidence by taking into account the totality of the available scientific data, and by weighing the evidence. In this context EFSA is invited to comment on the nature and quality of the totality of the evidence provided according to consistent criteria.
- The specific importance of the food for the claimed effect. For functions affected by a large number of dietary factors whether a reference to a single food is scientifically pertinent.

In addition, EFSA should consider the claimed effect on the function, and provide advice on the extent to which:

- the claimed effect of the food in the identified function is beneficial.
- a cause and effect relationship has been established between consumption of the food and the claimed effect in humans and whether the magnitude of the effect is related to the quantity consumed.
- where appropriate, the effect on the function is significant in relation to the quantity of the food proposed to be consumed and if this quantity could reasonably be consumed as part of a balanced diet.
- the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.
- the wordings used to express the claimed effect reflect the scientific evidence and complies with the criteria laid down in the Regulation.

When considering these elements EFSA should also provide advice, when appropriate:

- on the appropriate application of Article 10 (2) (c) and (d) in the Regulation, which provides for additional labelling requirements addressed to persons who should avoid using the food; and/or warnings for products that are likely to present a health risk if consumed to excess.

## **APPENDIX B**

### **EFSA DISCLAIMER**

The present opinion does not constitute, and cannot be construed as, an authorisation to the marketing of the food/food constituent, a positive assessment of its safety, nor a decision on whether the food/food constituent is, or is not, classified as foodstuffs. It should be noted that such an assessment is not foreseen in the framework of Regulation (EC) No 1924/2006.

It should also be highlighted that the scope, the proposed wordings of the claims and the conditions of use as proposed in the Consolidated List may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 13(3) of Regulation (EC) No 1924/2006.

## APPENDIX C

Table 1. Main entry health claims related to *Lactobacillus johnsonii* NCC 533 (La1) (CNCM I-1225), including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
896	Lactobacillus johnsonii NCC 533 (La1) (Pasteur culture collection CNCM I-1225)	Natural defence/immune system <u>Clarifications from MS:</u> Improved host defences against infectious agents As recommended by PASSCLAIM, the functional capacity of the immune system has been assessed by: - measuring specific cell functions ex vivo - measuring in vivo responses to challenge, e.g. change in antibody in blood or response to antigens - determining the incidence and severity of infections	- probiotic  '-increases your natural defences;  -actively supports your immune system;  -strengthens your immune defences.
		<b>Conditions of use</b>  - mind. 10E9 KBE/Tag, fermentierte Milch und sprühgetrocknet  - at least 109 cfu/day Fermented milk and spray-dried powder (supplement)	
ID	Food or Food constituent	Health Relationship	Proposed wording
900	Lactobacillus johnsonii NCC 533 (La1) (Pasteur culture collection CNCM I-1225)	Skin health <u>Clarification provided</u>  Skin Health. Improved skin response to UV/sun exposure assessed by measuring: - the antigen-presenting capacity in a mixed epidermal cell lymphocyte reaction (MECLR) - the erythematous and pigmentation response	'- probiotic -La1 helps to preserve skin health. + - helps to reinforce skin defences
		<b>Conditions of use</b>  – at least 5x10 <sup>9</sup> cfu/day, Powder  – at least 5x10 <sup>9</sup> cfu/day, Powder (supplement)	
		<b>Comments from Member States</b>  UK proposal identical to Dutch proposal	



## **GLOSSARY AND ABBREVIATIONS**

CFU	Colony-forming unit
CNCM	Collection Nationale de Cultures de Microorganismes
IgA	Immunoglobulin A
MED	Minimal erythematous dose
NCBI	National Center for Biotechnology Information